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Food Safety And Inspection Service
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AUDIT REPORT FOR AUSTRIA
MARCH 6 THROUGH MARCH 7, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Austria's Establishment 25-A from March 6 through March 7, 2000. One of the three establishments certified to export meat to the United States was audited.

The last audit of the Austrian meat inspection system was conducted in November 1999. Two establishments were audited and both were evaluated as acceptable/re-review. Establishment 25-A was certified to export meat to the United States on February 28, 2000, by Dr. Peter Vitus Stangle, Head of Department for Veterinary Services-Meat Hygiene/Residue Control (VSMHRC), in Austria. Establishment 25-A was audited as a special audit at the request of VSMHRC inspection officials.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Austrian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. Establishment 25-A was selected for on-site audit as requested. The third was conducted by on-site visits to establishment. The fourth was a visit to one private laboratory, culturing field samples for the presence of microbiological contamination with *Salmonella*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Austria's inspection system was assessed by evaluating these five risk areas.

During on-site establishment visit, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program

delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials this was the case with Establishment 25-A.

RESULTS AND DISCUSSION

Summary

Based on the performance of Establishment 25-A, Austria's "In-Plant Inspection System Performance" was evaluated as In-Plant System Controls not In Place.

Establishment 25-A was found to be unacceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

During this new audit, implementation of the required HACCP programs was found to be deficient in Establishment 25-A. Details are provided in the Slaughter/ Processing Controls section later in this report.

Entrance Meeting

On March 6, an entrance meeting was held at the Veterinary Services Office of the Federal Chancellery in Austria, and was attended by Dr. Peter Vitus Stangle, Head of Department for Veterinary Services-Meat Hygiene/Residue Control; Mr. Georg Brandl, MA, Veterinary Services-Veterinary Border Control and Dr. Faizur Choudry, International Audit Staff Officer. Topics of discussion included the following:

1. The audit itinerary and travel arrangements
2. Generic *E. coli* and *Salmonella* testing.
3. HACCP implementation
4. SSOP implementation
5. Enforcement – *Salmonella/*routine, Enforcement Report, Criminal Prosecution.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Austria's inspection system in November1999.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally

conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

No records review was conducted at the meat inspection headquarters or the inspection service or at a district or regional office

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Austrian as eligible to export meat products to the United States were full-time government employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Three establishments were certified to export meat products to the United States at the time this audit was conducted. Establishments 2 and 8 were audited by Dr. Oto Urban in November 1999 and one newly certified Establishment 25-A was visited for on-site audit by me. In Establishment 25-A, both VSMHRC inspection system controls and establishment system controls were not in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

Austria's microbiological testing for *Salmonella* was being performed in private laboratories. One of these, the Institute for Bio-Analysis and Hygiene in Perg, Upper Austria was audited. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratory was accredited/approved by the government.
2. The laboratories had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses were being reported simultaneously to the government and establishment.

Establishment Operations by Establishment Number

The following operations were being conducted in the one establishment:

Hogs slaughter, boning, and cutting in Establishment 25-A.

SANITATION CONTROLS

Based on the on-site audit of establishment 25-A, Austria's inspection service and establishment did not had adequate controls in place for lighting; maintenance and cleaning of over-product ceilings and equipment; product contact equipment; effective maintenance sanitation program; Pre-operational and operational SSOPs program; personnel protective coverings; cross contamination prevention; and condemned product control.

Sanitation Standard Operating Procedures (SSOPs)

Establishment 25-A was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with major variations. The daily pre-operational and operational SSOPs records did not reflect the actual sanitary conditions observed in Establishment 25-A.

Cross-Contamination

1. Dripping condensate from pipes, ceilings, and refrigeration units that were not cleaned/sanitized daily, was falling onto carcasses in the cooler. Old pieces of meat, blood, fat, mold, dirt, and black stains were observed on ceilings in the slaughter, boning, and offal rooms and coolers in Establishment 25-A. Neither establishment nor GOA officials took corrective actions.

2. Blood, fat, and fecal material were found on the automatic hog viscera conveyor after washing/sanitizing in the slaughter room. Neither establishment nor GOA officials took corrective actions.

Condition of Facilities Equipment

1. Overhead beams, pipes, and vent screens were observed with accumulations of fat, dirt and dust in the slaughter, boning, and offal rooms and coolers. A roller

conveyor for boxed edible product and cleaned edible product containers was found with pieces of fat, meat, dirt and dust, and water was dripping from containers onto the edible product stored underneath in the boning room and in one carcass cooler. Neither establishment nor GOA officials took corrective actions.

2. Numerous plastic cutting/boning boards in the boning and offal rooms were found with dried blood from previous days operation. The boards were deeply scored and in use with exposed product observed at the time of the review. Establishment officials ordered immediate correction and proposed preventive measures to GOA officials.

Product Protection & Handling

1. Personnel in the boning, offal and slaughter rooms were observed with worn out and deteriorated aprons. Establishment officials ordered prompt correction.

2. Hog carcasses were contacting work platform and employees boots at the retain carcass station in the slaughter room. Establishment officials proposed corrective and preventive measures to GOA inspection officials.

ANIMAL DISEASE CONTROLS

Austria's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

RESIDUE CONTROLS

Austria's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Austrian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals. The Veterinary Drug Residue Laboratory in Molding, Austria was not visited.

Please see microbiology laboratory audit section.

SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the Austrian inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem dispositions;

humane slaughter; postmortem inspection procedures; postmortem dispositions; pre-boning trim.

Control of condemned and inedible product: condemned carcasses, part of carcasses and other inedible products were not slashed and denatured prior to leaving the establishment. Neither establishment nor GOA inspection officials took corrective actions.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were audited and found to meet the basic FSIS regulatory requirements, with the following major variations:

1. The analysis did not include food safety hazards reasonably likely to occur.

2. The HACCP plan did not specify critical limits, monitoring procedures and the monitoring frequencies performed for each CCP adequately.

3. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed. Neither establishment personnel nor GOA inspection officials were performing adequate ongoing verification activities of the HACCP program.

4. Corrective actions to be followed in response to a deviation from a critical limit were not addressed adequately in the written HACCP plan.

5. Documentation of records for the HACCP program were not adequately maintained.

6. The zero-tolerance policy for visible fecal material on carcasses was not enforced by either establishment or GOA inspection officials, and no monitoring record was maintained to verify this activity.

7. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits were met and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product for each shipment eligible for export to the U.S. The auditor explained the

requirements for pre-shipment review in detail. GOA meat inspection officials indicated their intention to implement this requirement promptly.

GOA inspection and establishment officials agreed to take corrective actions for the discrepancies identified in the HACCP programs.

Testing for Generic *E. coli*

Austria has adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following equivalent measures:

1. Sample Collector: Private laboratory personnel take samples but not the government as stated in the criteria used for equivalence decisions for use of government employees in lieu of establishment employees:

2. The carcass selection was not being done randomly.

3. Establishment 25-A was using sponging method for sampling carcasses for *E.coli* and excision samples criteria was being used for the evaluation of the test results.

Additionally, establishments had adequate controls in place to prevent meat products intended for Austrian domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the Austrian meat inspection controls [ante-and post-mortem inspection procedures and dispositions, and inspection samples, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and inspection supervision and documentation and the importation of only eligible meat products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Establishment 25-A audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The *Salmonella* testing program was audited and found to meet the basic FSIS regulatory requirements. GOA inspection service has implemented *Salmonella* testing (one sample per month).

Austria has adopted the FSIS regulatory requirements for *Salmonella* testing with exception of the following equivalent measures:
Sample Collector: Private laboratory personnel take samples. The criteria used for equivalence decisions for use of establishment employees in lieu of government employees:

- *Salmonella* samples were analyzed
- The government uses test results to monitor establishment performance over time.
- The government takes immediate action any time an establishment fails to meet a S*almonella* performance standard.

LABORATORIES: Private Laboratories. The criteria used for equivalence decisions for the use of private laboratories in lieu of government laboratories are:

- The laboratory is accredited/approved by the government
- The laboratory has properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
- Results of analyses are reported to the government or simultaneously to the government and the establishment.

ENFORCEMENT STRATEGY: GOA inspection service has no regulation to enforce noncompliance when they determine that an establishment has not met the *Salmonella* standard. GOA inspection officials indicated that they would trace back the origin of the animal to the farm even if one *Salmonella* sample is found positive.

Species Verification Testing

At the time of this audit, Austria was exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by Dr. Fridrich Mayr, Austria's equivalent of Area Supervisors. He was a veterinarian with at least 10 years of experience.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were both announced and not announced in advance, and were conducted, at times, by individuals and at other times by a team of reviewers including a veterinarian from the State, at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the central office of the Veterinary Service in Vienna.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, a commission is empowered to conduct an in-depth review, and the results are reported to Dr. Roitner, Official Veterinarian for the State of Oberosterreich; Dr. Peter Vitus Stangl, Head of Department of Veterinary Services- Meat Hygiene/Residue Control; and Dr. Marina Mikula, Veterinary Medical Doctor, for evaluation; they formulate a plan for corrective actions and preventive measures.

After observing the internal reviewers' activities in the field, the auditor was confident in their professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Austria's internal review program as a whole.

Enforcement Activities

Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishments, inspection supervision as required, and adequate controls for security items, shipment security, species verification, and products entering the establishments from outside sources. GOA inspection service has no regulation to enforce noncompliance when they determine that an establishment has not met the *Salmonella* standard. GOA inspection officials indicated that they would trace back the origin of the animal to the farm even if one *Salmonella* sample is found positive.

I did not have time to get information in detail for both administrative and criminal enforcement of laws and regulations.

Exit Meetings

An exit meeting was conducted in the inspection office of Establishment 25-A on March 7, 2000. The Austrian participants were Dr. Werner Roitner, Regional Supervisor; Dr. Friedrich Mayer, Manager and Dr. Faizur R. Choudry, International Audit Staff Officer.
The individual audit findings including the HACCP program were discussed, as enumerated in the body of this report. The Austrian officials agreed to take the necessary steps to ensure that corrective actions and preventive measures, as promised during the audit and exit meetings in the establishment, would be implemented.

The following major deficiencies were discussed:

1. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed. Neither establishment nor GOA inspection officials

were performing adequate ongoing verification activities of HACCP program, in Establishment 25-A.

2. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit are not addressed adequately in the written HACCP plan.

3. The zero-tolerance policy for visible fecal material on carcass was not enforced by either establishment or GOA inspection officials, and no monitoring record was maintained to verify this activity.

4. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail and GOA meat inspection officials indicated they intend to implement this requirement promptly.

5. Condemned product controls: condemned carcasses, part of carcasses and other products were not slashed and denatured prior to leaving the Establishment 25-A. Neither establishment nor GOA inspection officials took corrective actions.

6. The daily pre-operational and operational SSOP records did not reflect the actual sanitary conditions observed at the time of the review.

Mr. Walter Krucsay, Agricultural specialist, U.S. Embassy, Vienna was briefed per telephone regarding the delistment of Establishment 25-A on March 7, 2000.

CONCLUSION

Establishment 25-A was found to have ineffective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. One establishment was audited and was evaluated as unacceptable. The deficiencies encountered during the on-site establishment audit, in Establishments 25-A, were not adequately addressed to the auditor's satisfaction. The GOA meat inspection officials reinforced the assurances made by field personnel during and at the conclusions of the on-site audit of Establishment 25-A and stated that they would ensure prompt compliance.

The major deficiencies were the following:

1. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed. Neither establishment nor GOA inspection officials

were performing adequate ongoing verification activities of HACCP program, in Establishment 25-A.

2. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit are not addressed adequately in the written HACCP plan.

3. The zero-tolerance policy for visible fecal material on carcass was not enforced by either establishment or GOA inspection officials, and no monitoring record was maintained to verify this activity.

4. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail and GOA meat inspection officials indicated to implement this requirement promptly.

5. Condemned product controls: condemned carcasses, part of carcasses and other products were not slashed and denatured prior to leaving the Establishment 25-A. Neither establishment nor GOA inspection officials took corrective actions.

6. The daily pre-operational and operational SSOP records did not reflect the actual sanitary conditions observed at the time of the review in Establishment 25-A.

Dr. Faizur R Choudry
International Audit Staff Officer

(signed) Dr. Faizur R. Choudry

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing
E. Laboratory audit form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)
H. FSIS Response(s) to Foreign Country Comments (when it becomes available)

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used included the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. Sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. Identified	7. Docu-mentation done daily	8. Dated and signed
025-A	√	√	√	√	√	√	√1	√

1. The daily pre-operational and operational SSOP records did not reflect the actual sanitary conditions observed in the establishment.

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. Species sampled	5. Sampling at the req'd freq.	6, Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
025-A	√	√	√	√	√	√	√1	√	√2	√

1. The carcass selection was not being done randomly.
2. Establishment 025-A, that the method for excising carcasses for *E. coli* sampling was used.

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. TIF-119) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or does not include records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. act's are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
025-A	√	√	√1	√	√	√	√2	√3	√	√4	√5	√

1. The analysis did not include food safety hazards reasonably likely to occur

2. The HACCP plan did not specify critical limits, monitoring procedures and the monitoring frequencies performed for each CCP adequately.

3. Corrective actions to be followed in response to a deviation from a critical limit are not addressed adequately in the written HACCP plan

4. Verification procedures and the frequencies with which these procedures will be performed, were not addressed adequately in the written HACCP plan.

5. Documentation of records for HACCP program was not adequately maintained.

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
025-A	√	√	N/A	√	√	√